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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,991	06/09/2000	John E. Adamou	469201-475	2154

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Alan J Grant Esq
Carella Byrne Bain Gilfillan Cecchi
Stewart & Olstein
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/590,991	Adamou et al.
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 29, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 4-15, and 17-32* is/are pending in the application.

4a) Of the above, claim(s) *5-15, 17-22, and 25-32* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 4, 23 and 24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APLLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 05/29/02 (paper no. 8) in response to the non-final Office Action mailed 12/21/01 (paper no. 6). With this, Applicants have amended the specification.

Status of Claims

2) Claims 2, 3 and 16 have been canceled via the amendment filed 05/29/02.

Claim 1 has been amended via the amendment filed 05/29/02.

New claims 23-32 have been added via the amendment filed 05/29/02.

Claims 1, 4-15 and 16-32 are pending.

Claims 25-32 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1, 4, 23 and 24 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

5) The objection to the drawings made in paragraph 3 of the Office Action mailed 12/21/01 (paper no. 6) is maintained fro reasons set forth therein. Applicants request that submission of drawings be delayed until such time as allowable subject matter has been found. Applicants are asked to note the changes effected 03 May 2001, particularly the changes to the 'Timing of Corrections':

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. *Correction of Informalities* -- 37 C.F.R 1.85; 1097 O.G. 36

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 C.F.R 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, Applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, Applicant should file corrected drawings as soon as possible. Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

6) The objection to claim 4 made in paragraph 13 of the Office Action mailed 12/21/01 (paper no. 6) is withdrawn.

Objection(s) Moot

7) The objection to claim 16 made in paragraph 13 of the Office Action mailed 12/21/01 (paper no. 6) is moot in light of Applicants' cancellation of the claim.

Objection(s) Withdrawn

8) The objection to the specification made in paragraph 5 of the Office Action mailed 12/21/01 (paper no. 6) is withdrawn in light of Applicants' amendments to the specification.

Rejection(s) Moot

9) The rejection of claims 2, 3 and 16 made in paragraph 6 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 16 made in paragraph 7 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 112, first paragraph, as being non-enabled, with regard to the scope, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 16 made in paragraphs 9(b) and 9(c) of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

12) The rejection of claims 2 and 3 made in paragraph 9(d) of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

13) The rejection of claims 2 and 3 made in paragraph 11 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 102(a) as being anticipated by Bethe *et al.* (EMPL AF127143, submitted February 1999), is moot in light of Applicants' cancellation of the claims.

14) The rejection of claims 2 and 16 made in paragraph 12 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 102(b) as being anticipated by Kunsch *et al.* (WO 98/18930), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

15) The rejection of claim 1 made in paragraph 9(a) of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light

of Applicants' amendments to the claim.

16) The rejection of claim 4 made in paragraph 6 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 112, first paragraph, as being non-enabled, is withdrawn in light of Applicants' amendments to the base claim.

17) The rejection of claim 1 made in paragraph 11 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 102(a) as being anticipated by Bethe *et al.* (EMPL AF127143, submitted February 1999), is withdrawn.

18) The rejection of claim 1 made in paragraph 12 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 102(b) as being anticipated by Kunsch *et al.* (WO 98/18930), is withdrawn in light of Applicants' amendments to the claim.

Rejection(s) Maintained

19) The rejection of claim 1 made in paragraph 6 of the Office Action mailed 12/21/01 (paper no. 6) under 35 U.S.C. § 112, first paragraph, as being non-enabled, is maintained for reasons set forth therein and herebelow.

New claim 23 is now added to this rejection.

Applicants state that they believe that a vaccine containing a polypeptide comprising a sequence at least 95% identical to SEQ ID NO: 6 is supported in Figure 1, 3 and 4A, which allegedly show the ability of Sp128 (SEQ ID NO: 6) to protect mice against infection by a heterologous pneumococcal strain. Applicants also point to Figures that show the results obtained with Sp130, i.e., SEQ ID N: 8. Applicants assert that the 'variation in reactivity is believed to justify a vaccine containing a polypeptide sequence having at least 95% identity to Sp128 (SEQ ID NO: 6)".

Applicants' arguments have been carefully considered, but are non-persuasive. Firstly, claim 1, as amended, is required to contain a polypeptide comprising an amino acid sequence 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO: 6 and is present in an amount to "elicit production of protective antibodies in an animal against *Streptococcus pneumoniae*". Any descriptive support in the specification for a mere vaccine containing a polypeptide sequence having at least 95% identity to SEQ ID N: 6 would not justify such a vaccine with protective

ability absent a concrete showing of protection. Secondly, neither Figures 1, 3 and 4A, nor the descriptions for these Figures identify the polypeptide used in protection experiments to be having 95%, 96%, 97%, 98% or 99% identity to SEQ ID NO: 6. Figures that provide data about Sp130 polypeptide cannot support a claim that recites SEQ ID NO: 6. As explained in detail in paragraph 6 of the Office Action mailed 12/21/01 (paper no. 6), when the art has established that even a single amino acid dissimilarity can drastically change the biologic functions of a polypeptide, there is no guarantee that a polypeptide with a dissimilarity as mush as 1-5% would still maintain its protective ability and/or the pneumococcal specificity. See that paragraph 6 of the Office Action mailed 12/21/01 (paper no. 6) for a detailed explanation, including the unpredictability factor.

Applicants further state, on page 6 (fourth full paragraph) of their amendment filed 05/29/02, that the vaccine as claimed in the amended claim 1 containing a polypeptide that is 95% identity to SEQ ID NO: 6 is 'required to induce production of antibodies when administered to a mouse'. However, on the contrary, the vaccine as claimed in the amended claim 1 and the new claim 23 is required to induce 'protective' antibodies.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments and/or submission of new claims.

Rejection(s) under 35 U.S.C § 112, First Paragraph (Non-enablement)

20) Claim 23 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See paragraph 19 above and paragraph 6 of the Office Action mailed 12/21/01 (paper no. 6) for a detailed explanation.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

21) Claims 1 and 4 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claim 1 now includes the limitations: vaccine comprising a polypeptide comprising an amino acid sequence "at least 95% identical" to SEQ ID N: 6 and "present in a carrier in an amount effective to elicit production of protective antibodies in an animal against *Streptococcus pneumoniae*". Applicants point to page 18, lines 22-25 and Figures 1, 3 and 4A as providing support for the added limitation. However, there is no descriptive support in these parts of the specification for a polypeptide vaccine comprising an amino acid sequence 95%, 96%, 97% or 99% identical to SEQ ID N: 6 and "present in a carrier in an amount effective to elicit production of protective antibodies in an animal against *Streptococcus pneumoniae*". Figures appear to provide data obtained with a polypeptide that is 100% identical to SEQ ID NO: 6. Therefore, the above-identified new limitations in claim 1 are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

22) Claims 23 and 24 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 23 includes the limitations: "polypeptide comprising an amino acid sequence at least 95% identical to SEQ ID N: 6 wherein said polypeptide elicits production of antibodies that protect against infection by *Streptococcus pneumoniae* when administered to an immunocompetent animal". However, there appears to no descriptive support in the specification for a polypeptide comprising an amino acid sequence 95%, 96%, 97% or 99% identical to SEQ ID N: 6 wherein the polypeptide elicits production of antibodies that protect against infection by *Streptococcus pneumoniae* when administered to an immunocompetent animal. The narrower limitation "immunocompetent animal" does not appear to have descriptive

support in the specification, as originally filed. Therefore, the above-identified limitations in claim 23 are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

23) Claims 1, 4, 23 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1 and 23 are vague in the recitation "identical to SEQ ID NO: 6" without reciting that the sequence is an amino acid sequence. In order to distinctly claim the subject matter of the instant invention and to be consistent with the language used in dependent claims, it is suggested that Applicants replace the recitation with --identical to the amino acid sequence of SEQ ID NO: 6--.

(b) Claims 4 and 24, which depend from claims 1 and 23 respectively, are also rejected as being indefinite because of the vagueness identified above in the base claim(s).

Remarks

24) Claims 1, 4, 23 and 24 stand rejected.

25) The Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

27) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August, 2002

S. DEVI, PH.D.
PRIMARY EXAMINER